REMARKS

Claims 1, 3-4, 6-7, 9-11, 13-15, 19 and 23-26 were pending and claims 10-11 and 13-15 were withdrawn from consideration. By virtue of this amendment, claims 1, 6, 19 and 23 have been amended and claims 9-11 and 13-15 have been cancelled, without prejudice. New claim 27 has been added. Accordingly, upon entry of this amendment, claims 1, 3-4, 6-7, 19 and 23-27 are pending and under consideration in the present application.

The claim amendments and the new claim are fully supported by the specification. No new matter has been introduced. In particular, claims 1 and 6 have been amended to specify that the compound being administered is an antibody as previously specified in claim 9. Claim 1 has been further amended to specify that the animal is not infected with HIV. Support for this amendment can be found, for example, in paragraph [0070] of the published application (U.S. Publication No. 2005/0118168). See *In re Johnson,* 558 F.2d 1008 (CCPA 1977). Claims 19 and 23 have been amended to depend from claim 1 since claim 9 has been cancelled. Support for new claim 27 can be found, for example, in paragraph [0063] of the published application.

Amendment of claims should in no way be construed as an acquiescence to any of the rejections. The amendments to the claims are being made solely to expedite prosecution of the present application. Applicants reserve the option to further prosecute the same or similar claims in the instant or in a subsequent patent application.

Applicants respectfully request reconsideration in view of the following remarks. Issues raised by the Office Action will be addressed below in the order they appear in the Office Action.

Claim Rejections Under 35 U.S.C. §112, First Paragraph - Enablement

Claims 1, 3-4, 6-7, 9, 19 and 23-26 were rejected under 35 U.S.C. §112, first paragraph, for purposes of enablement. The Examiner alleges that no specific population has been defined such that HIV infection is excluded, that no correlation between *in vitro* and *in vivo* data has been shown, and that Applicants have not demonstrated that a compound that binds to SEQ ID NO: 2 results in a reduction of the immune response. Applicants respectfully traverse the rejection.

Applicants submit that a specific population has been defined by the claims. In particular, claim 1 has been amended to recite a method for reducing an immune response in an animal by inhibiting an interaction between a dendritic cell and a T cell, comprising administering to an animal *in need of reducing said immune response* an antibody which binds to a protein with the amino acid sequence of SEQ ID NO: 2 (DC-SIGN) on the surface of a dendritic cell, wherein said antibody reduces one or more interactions between a dendritic cell and a T cell thereby reducing an immune response in the animal. *See, e.g., Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329, 1333 (Fed. Cir. 2003) (stating that "the claims' recitation of a patient or a human 'in need' gives life and meaning to the preambles' statement of purpose [because] it is a statement of the intentional purpose for which the method must be performed"); *Rapoport v. Dement*, 254 F.3d 1053 (Fed. Cir. 2001). Accordingly, the claim is directed to a population of patients that are *in need of reducing said immune response*. As described in the specification, examples of patients in need of a reduced immune response include patients suffering from an autoimmune disease or patients suffering from an allergy. In addition, Applicants have amended claim 1 to specify that the anti-DC-SIGN antibody is administered to animals that are *not* infected with HIV. Thus, Applicants submit that the claims, as amended, define a specific population, and the rejections are rendered moot in light of the amendments.

Applicants further submit that they have sufficiently demonstrated that an antibody that binds to SEQ ID NO: 2 results in a reduction of the immune response. In particular, the instant application sets forth several examples and presents *in vitro* data derived from cell based assays demonstrating that the interaction between dendritic cells and T cells is mediated by an interaction between DC-SIGN on the surface of the dendritic cells and an ICAM receptor on the surface of the T cells. Furthermore, the application demonstrates that an anti-DC-SIGN antibody can inhibit the interaction between DC-SIGN and an ICAM receptor (see e.g., Example 2, paragraph [0100] and Figures 2A and 2C). These assays are representative of what occurs *in vivo*, i.e., there are interactions between DC-SIGN and ICAM receptors on the surface of T cells, and the interactions induce T cell proliferation and initiate immune response (see e.g., paragraph [0093] of the instant application). Therefore, the application teaches and enables reducing an immune response in an animal in need thereof by inhibiting an interaction between a dendritic cell and a T cell. A person

of ordinary skill in the art, without undue experimentation or inventive skills, can make and use the claimed methods based on the *in vitro* data and other disclosure provided by the application.

Finally, Applicants submit that they have provided evidence that one of skill in the art would expect that the *in vitro* evidence provided in the specification is representative of what occurs *in vivo*. The Office has not provided any evidence that one of skill in the art would find a lack of correlation between the *in vitro* data and *in vivo* results. In particular, scientific literature studying the interactions between dendritic cells and T cells shows that *in vitro* results are consistent with *in vivo* results in this area. For example, Ingulli, et al., *J. Exp. Med.*, vol 185, 2133-2141 (1997) ("Ingulli," submitted as Exhibit A attached to the response dated April 28, 2008) demonstrates that antigen-bearing dendritic cells directly interact with naive antigen-specific T cells (Ingulli, abstract). This result is consistent with *in vitro* experiments suggesting that dendritic cells are initiating APCs for T cell responses (Ingulli, page 2133, left column). In particular, Ingulli states that "[t]he capacity of individual OVA peptide-pulsed DC to simultaneously interact with many antigen-specific T cells in vivo is reminiscent of ... in vitro studies" (Ingulli, page 2138, right column). Similarly, Steinman, *Cell*, vol. 100, 491-494 (2000) ("Steinman," submitted as Exhibit B attached to the response dated April 28, 2008) summarizes several *in vivo* studies that corroborated previous *in vitro* results (Steinman, page 492, right column). Thus, results from *in vitro* studies in this area are well recognized in the art as predictive of *in vivo* events.

The Office bears the initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by the claims is not enabled by the description provided in the specification of the application (see *In re Brana*, 51 F.3d 1560, 1566 (Fed. Cir. 1995); *In re Wright*, 999 F.2d 1557, 1561-1562 (Fed. Cir. 1993)). Additionally, the Office has the burden to provide reasons for a conclusion of lack of correlation for an *in vitro* or *in vivo* animal model (see MPEP 2164.02). This burden has not been met in this case.

The Examiner relies on Steinbrook as allegedly showing that applicants' *in vitro* testing results do not correlate with *in vivo* efficacy (see Office Action dated January 28, 2008). The Examiner states that Steinbrook shows the unpredictability in the art of reducing HIV infection. However, as discussed above, the claims are directed to a method for reducing an immune response

in a *non-HIV infected* animal by inhibiting an interaction between a dendritic cell and a T cell. Furthermore, Steinbrook does not discuss the correlation between *in vitro* and *in vivo* results related to inhibition of the interactions between DC-SIGN and a T cell. Accordingly, Steinbrook fails to provide any specific evidence to show that Applicants' *in vitro* testing results do not correlate with *in vivo* efficacy.

Accordingly, the Office has not met its burden in challenging the enablement of the instant claims and therefore the rejection cannot stand and should be withdrawn. For the reasons presented above, applicants submit that the claims fully comply with the enablement requirement under 35 U.S.C. § 112, first paragraph. Reconsideration and withdrawal of this rejection are respectfully requested.

Claim Rejections Under 35 U.S.C. §102

Claims 1, 3-4, 6-7, 9, 19 and 24-26 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Curtis (WO93/01820).

Applicants respectfully disagree with the rejection. However, in an effort to expedite prosecution, claim 1 has been amended and the amendment is believed to obviate the rejection. In particular, claim 1 has been amended to recite that the method involves administering an *antibody* that binds to a protein with SEQ ID NO: 2 (DC-SIGN) to reduce an immune response in a *non-HIV infected* animal. Curtis clearly does not teach or suggest such a method. In particular, Curtis discloses a method for inhibiting HIV infection of *mammalian cells* by contacting the cells with an appropriate inhibitor of gp120r binding. The inhibitor prevents gp120, a glycoprotein on the HIV envelope, from binding to gp120r and physically prevents HIV from entering the cell. Curtis teaches that inhibitors of gp120r binding include mannose carbohydrates, fucose carbohydrates, plant lectins, and antibiotics such as pradimicin A (see e.g., top of page 4). Curtis never teaches that an antibody to gp120r could be used as an inhibitor to prevent gp120 binding to prevent HIV infection. In addition, Curtis never teaches or suggests administering an antibody that binds to gp120r to a *non-HIV infected animal.* Accordingly, Curtis fails to teach or suggest each element of the currently pending claims.

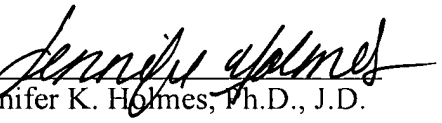
A claim is anticipated only if each and every element of the claim is found in a single prior art reference. The Curtis reference does not teach each and every element of the claims as amended. Therefore, reconsideration and withdrawal of the rejection of the claims under 35 U.S.C. §102(b) is respectfully requested.

CONCLUSION

In view of the above amendments and remarks, Applicants believe the pending application is in condition for allowance. Early and favorable consideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000. Applicants believe no fees are due other than specifically itemized on the accompanying fee transmittal. Should an extension of time be required, Applicants hereby petition for same and request that the extension fee and any other fee required for timely consideration of this submission be charged to **Deposit Account No. 18-1945**, under Order No. ALXN-P02-089 from which the undersigned is authorized to draw.

Dated: December 4, 2008

Respectfully submitted,

By 

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